REMARKS

Claims 19-21 and 23-30 are pending.

Claims 20-21, 23-24, and 27-30 have been withdrawn from consideration.

Support for the amendment to Claim 19 is found on page 5, lines 13-17 ("with proteins containing at least a portion of these sequences") and page 8, lines 5-11 ("antigenic determinant known to induce a strong immune response, i.e. the antigenic determinant of one of the proteins with SEQ ID N°2 or SEQ ID N°3, with an antigenic determinant inducing a weak response when it is injected alone").

No new matter is believed to have been added by this amendment.

Entry of the amendment is requested. At minimum, Applicants request that the Amendment be entered for purposes of an Appeal as the amendment simplifies the issues.

The rejections of Claims 19 and 25-26 under 35 U.S.C. § 112 second paragraph is no longer applicable in light of the amendment submitted herein. Likewise, the rejection of Claims 19, 25 and 26 under 35 U.S.C. § 112, first paragraph ("New matter") is no longer applicable in light of the amendment submitted herein.

The rejection of Claims 19, 25 and 26 under the doctrine of obviousness-type double patenting in view of the parent application, now U.S. patent no. 6,676,945 is addressed by the Terminal Disclaimer filed herewith.

The rejection of Claims 19, 25 and 26 as allegedly failing to be adequately enabled under 35 U.S.C. § 112, first paragraph is no longer applicable in light of the amendments submitted herein. Specifically, the rejection is based on an alleged lack of enablement for a "portion" of the protein or "conservative substitutions" in the protein. However, Claim 19 no longer includes those phrases. As this rejection may be applied to the current Claim 19, the rejection is untenable in light of the disclosure provided in the specification supporting the

synthesis and use of a hybrid protein with an antigenic protein fragment of SEQ ID NOS:2 or 3; and a polypeptide comprising an antigenic determinant which is able to induce an immune response in an animal.

As described on page 7, lines 19-21 (emphasis added):

> Proteins with the sequences SEQ ID N°2 or SEQ ID N°3 have the advantage of being recognized by the antibody present in tuberculosis patients and **thus constitute a priori highly immunogenic antigens**.

Further, as described in the specification on page 8, lines 8-10 (emphasis added):

> The combination of the **antigenic determinant** of one of the proteins SEQ ID N°2 or SEQ ID N°3 allows an amplification of the immune response against the second antigenic determinant of the hybrid protein.

In other words, what the specification teaches is that an antigenic determinant of SEQ ID NOS: 2 or 3, i.e., an epitope of the protein or the protein fragment of SEQ ID NOS:2 or 3 that induce an immune response. There cannot be any question that the specification coupled with the common knowledge in the field provides sufficient guidance to make the claimed hybrid proteins (e.g., see pages 12-30 describing isolation of proteins and preparing recombinant plasmids).

Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claims 19 and 25-26 under 35 U.S.C. § 103(a) over Wieles in view of Marchal, as evidenced by U.S. Patent No. 6,060,259 is no longer applicable in light of the amendments submitted herein. More specifically,

The proteins in Wieles and Marchal are N-terminal amino acid sequences. There is no evidence of record to conclude that Wieles describes an antigenic protein fragment as claimed. For this reason alone, Applicants request that the rejection be withdrawn.

As duly noted by the Office, Wieles does not describe a hybrid protein. For this, The Office suggests that one would have put the Wieles protein into a hybrid based on the teachings of Marchal. Applicants disagree.

As stated by Wieles, the amino acid homology between these sequences is 47% (see Wieles et al., Abstract, page 255, left column and figure 4). Furthermore, the Wieles protein originates from *Mycobacterium leprae*, whereas the protein in Marchal originates from *Mycobacterium bovis* BCG. There is nothing in either document which would reasonably suggest replacing the protein in Marchal with **a completely different protein** from Wieles. Furthermore, there is nothing in the combination of publications which describes or suggests selecting antigenic protein fragments of SEQ ID NOS:2 or 3 because (1) neither describes SEQ ID NO:2 or 3; (2) neither describes antigenic protein fragments of SEQ ID NO:2 or 3; and (3) neither describes or suggests the advantages of the claimed invention: inducing a strong immune response against the amino acid sequences of SEQ ID NO:2 or SEQ ID NO:3. Accordingly, the claims could not have been obvious in view of the combination of cited publications and as such withdrawal of this ground of rejection is requested.

Applicants request allowance of the pending claims.

Respectfully submitted,

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